UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
----------X
MARY ELLEN WALSH,
,

Plaintiff,

-against-

EMPIRE BLUE CROSS/BLUE SHIELD, INC.
EMPIRE HEALTHCHOICE ASSURANCE, INC.
and EMPIRE HEALTHCHOICE HMO, INC.

Defendants.
----------X

MEMORANDUM & ORDER
16-CV-3746 (DRH) (ARL)

APPEARANCES:

For Plaintiffs:
Joseph C. Stroble, Esq.
P.O. Box 596
40 Main Street
Sayville, NY 11782

For Defendants:
Fox Rothschild LLP
49 Market Street
Morristown, New Jersey 07960-5122
By: Brian D. Sullivan, Esq.

HURLEY, Senior District Judge:

Plaintiff Mary Ellen Walsh ("Plaintiff" or "Walsh") commenced this action against defendant Empire Healthchoice Assurance, Inc. ("EHA"), Empire Health Choice HMO ("HMO") and Empire Blue Cross/ Blue Shield ("BC/BS") (collectively "Defendants") under section 502(a)(1)(B) of the Employee Retirement Income Security Act of 1974 ("ERISA") to recover benefits she contends are due her under the terms of an employee welfare benefit plan. Presently before the Court is Plaintiff's motion and Defendants' cross-motion for summary

judgment. For the reasons set forth below, Plaintiff's motion is denied and Defendant's motion is granted.

BACKGROUND

The following facts are undisputed unless otherwise noted.[1]

I. The Parties

Plaintiff is a beneficiary of the Plumbers Local Union No. 1 Welfare Fund (the "Welfare Fund") an employee welfare benefit plan within the meaning of section 3(1) of ERISA. On February 24, 2016 when the services at issue were provided, she was eligible for benefits in accordance with the terms of the self-insured plan of benefits (the "Plan") sponsored by the Welfare Fund. EHA performs claims adjudication services and makes its network of hospitals, doctors and other medical providers available to the Welfare Fund's participants and beneficiaries in accordance with an administrative services agreement with the Welfare Fund. EHA does not act as an insurer with respect to the Welfare Fund or its Plan. When EHA approves a claim for payment, the Welfare Fund pays the claim and thus EHA has no financial stake in how claims are adjudicated. (Defs.' 56.1 Statement ¶¶ 3-6.) HMO has no relationship to Plaintiff or with the Welfare Fund and that BC/BS is not a legal entity but rather a name under which EHA and HMO conduct business. (Langhorne Aff. (DE 27-4) ¶¶ 4, 5.)

II. The Plan

The benefits to which Plaintiff is entitled to under the Plan are set forth in a booklet distributed by the Welfare fund (the "Plan Document"). The Plan cover both in-network and out-of-network benefits. When participants and beneficiaries use in-network providers for surgical

[1] Contrary to this Court's Individual Practice Rules, Plaintiff did not file a response to Defendants' Rule 56.1 Statement and failed to cite any record evidence to support her Rule 56.1 Statement. Despite these failings, this Court reviewed the entire administrative record and is satisfied that, unless otherwise noted, the recited facts are not controverted.

procedures, as Plaintiff did here, there are no claim forms, no deductibles, and no co-pays. The Plan document sets forth the benefits to which participants and beneficiaries are entitled and the Plan does not pay benefits unless the charges are covered by the Plan. Among other things, the Plan does not cover treatments and drugs that are experimental, investigational or part of a research program, which are defined as follows:

- any treatment not proven in an objective manner to have benefits for the patient;
- any treatment that is restricted to use in a medical facility engaged primarily in carrying out scientific studies;
- any treatment, drug or supply which is not recognized as acceptable medical practice in the United States;
- any items requiring governmental approval which was not granted at the time the services were rendered;
- any services supplied or available only on approval of an Institutional Review Board (as required by Federal statute), including ones that require completion of an informed consent for experimentation on human subjects (as required by Federal regulations);
- any treatment that involves drugs not approved by the Food and Drug Administration (FDA), including dosages, combinations and uses that are not approved;
- any new drug or devise for which an investigational application has been filed with the FDA;
- any treatment that is available only through participation in FDA Phase I or Phase II clinical trials or Phase III experimental research clinical trial sponsored by the National Cancer Institute; and/or
- any services or supplies that have protocols or consent documents describing them as an alternative to more conventional therapies.

(Defs.' 56.1 Statement ¶¶ 7-11.)

III. The Treatment at Issue and the Adjudication of the Claims

On January 16, 2014, Plaintiff was diagnosed with gastroparesis.[2] Gastroparesis is defined as "[w]eakness of gastric peristalsis, which results in delayed emptying of the bowels."

[2] Plaintiff states that she was also diagnosed with "dysphagia," apparently a medical term used to describe difficulty swallowing, but cites nothing in the record to support that assertion. In any event, she has maintained throughout the pendency of her claims and appeals that the Botox Injections were intended to treat her gastroparesis. Therefore whether or not she was diagnosed with dysphagia is not material to the issues at bar.

Steadman's Medical Dictionary, at 793 (28th Ed.) As treatment therefor Plainiff received five intrapylonic injections of botulinum toxin ("Botox Injections"). The Botox Injections, a surgical procedure, were performed at St. Catherine of Sienna, an in-network provider, on February 11, 2014; May 23, 2014; September 12, 2014; November 25, 2014; and February 24, 2015. For the first four Botox Injections, the provider submitted claims to EHA for reimbursement of "Surgery-Pharynx/Esph," and certain ancillary charges, but did not seek reimbursement for the botulinum toxin (the "Botox") that was injected into Plaintiff's esophagus. The claims for the first four Botox Injections were processed by EHA without issue. Plaintiff's total financial responsibility for the services provided was zero. (Defs.' 56.1 Statement ¶¶ 12-16.)

In its claim for the fifth injection, the provider included for the first time a line item charge for the Botox. Believing that there might be an issue as to whether the procedure was covered, EHA paid the claim, subject to retrospective review whereby it would be able to recoup any overpayment from the provider in accordance with the participation agreement. Thereafter a revised "Institutional Explanation of Benefits" was issued to the provider in which EHA adjusted it payment for the fifth Botox Injection because the services had been determined to be investigational. Plaintiff bore no financial responsibility for the fifth Botox Injection (consistent with the terms of the Plan) but was notified of the decision both in an Explanation of Benefits and a letter dated April 7, 2015 from Anthem.[3] (Defs.' 56.1 Statement ¶¶ 17-22.)

IV. The Administrative Appeals

A. The First Appeal

Although she had no financial responsibility for the fifth injection, Plaintiff appealed the retroactive denial of coverage and submitted a letter in support of her appeal. Included in the

[3] Anthem UM Services, Inc. ("Anthem") provides utilization management services for EHA and issued correspondence regarding Plaintiff's claim and administrative appeals.

letter were several articles from medical journals that discussed the use of Botox Injections to treat gastroparesis. In an article published in 2008, the authors state that Botox Injections have been reported to improve both symptoms and gastric emptying in an uncontrolled series of between three and 63 patients, but acknowledge that a more recent double-blind controlled crossover study found no improvement over the use of a placebo. (AR[4] 410.) In an excerpt from a 2007 report regarding the double-blind controlled crossover study referenced in the 2008 article, the individuals who conducted that study acknowledge that their study "failed to demonstrate a superior effect of [Botox Injections] over placebo in a group of patients with gastroparesis of predominantly idiopathic origin", and "does not support unselected use of [Botox] in gastroparesis. They further concluded, "additional research is needed to establish the use of [Botox] injection in population with a higher likelihood of, or with established pyloric dysfunction." (AR 419.) In the January 2013 article from the American Journal of Gastroenterology submitted by Plaintiff, the authors noted that two double-blind, placebo-controlled studies have shown some improvements in gastric emptying, but no improvement in symptoms compared with placebo. Thus, they concluded that "[Botox Injection] is not recommended as a treatment for gastroparesis, although there is a need for further study in patients with documented pylorospasm." (AR 456.) (Defs.' 56.1 Statement ¶¶ 24-26.)

By letter dated June 12, 2015, Plaintiff was advised that her appeal was denied and the previous coverage decision was not being changed because Botox is considered investigational for gastroparesis. The denial was based on the Plan's "medical policy DRUG .00006, botulinum toxin." That policy lists the uses for which Botox is classified as medically necessary as well as uses for which it is considered investigational and not medically necessary. With respect to

[4] AR refers to the administrative record (DE 22-1 to 22-4).

gastroparesis, the policy states it is investigational and not medically necessary. The policy provides the following rationale for this conclusion:

> Botulinum toxin has been researched as a treatment of gastroparesis. Through upper endoscopy, botulinum toxin has been injected into the pylorus to relax the muscle and speed emptying of gastric contents. The literature consists of several case series ranging in size from 3 to 20 individuals. Although the results show some positive effect after treatment with botulinum toxin, larger controlled trials are needed to determine the efficacy of this treatment method for gastroparesis [citing](Friedberg, 2004).

(Defs.' 56.1 Statement ¶¶ 27-29.)

On June 9, 2015, and again on June 10, 2015, Plaintiff spoke to EHA representatives, both of whom advised her that if she needed future Botox Injections, her provider should initiate a preauthorization request for the drug, and that no pre-authorization request had been submitted. (Defs.' 56.1 Statement ¶ 30.) Although Plaintiff asserts she requested pre-certification for further Botox endoscopy treatments which requests were denied (Walsh Aff. (DE 26-2) ¶11), there is nothing in the administrative record indicating that any pre-authorization requests for additional Botox treatments were made. (Defs.' 56.1 Statement ¶ 31.)

B. The Second Appeal

Plaintiff initiated a second appeal by letter dated August 15, 2015. On October 26, 2015, Zvi Alpern, M.D., the physician who had administered the Botox Injections, submitted a letter in support of Plaintiff's second appeal, the text of which reads as follows:

> 45-year-old woman with long history of insulin-dependent diabetes mellitus and peripheral neuropathy felt to be helped by Botox injection for gastric mobility disorder.
>
> I am aware of a small double blind study which did not show advantage to the treatment over placebo.
>
> In my opinion the study was too small to make a definite conclusion.

> There are reports of its beneficial effect. A study from the University of Michigan suggested that some people may need higher doses to respond. I have enclosed a study that was completed by Radoslav Coleski MD, Michele A. Anderson MD, and William L. Hasier for your review and consideration.

(Defs.' 56.1 Statement ¶¶ 32-35; AR 284.) The article referenced by Dr. Alpern contains a retrospective analysis of 179 gastroparetics that underwent Botox Injections and concluded that the findings "provide the foundation for large controlled trials of high-dose [Botox] in selected gastroparesis subsets." (AR 285, *see* also AR 292.) Paul Leva, M.D., the primary care physician who referred Plaintiff to Dr. Alpern, submitted a letter stating

> [Plaintiff] is a patient of mine who is a severe diabetic with gastroparesis. She is constantly vomiting and is in pain. The only relief she gets is with botox. Since botox is considerably less than surgery, it should not be denied. Her only option at this time is botox.

(Defs.' 56.1 Statement ¶36, AR 309.)

Anthem (on behalf of EHA) advised Plaintiff, by letter dated November 24, 2015,that her second level appeal had been reviewed by a Medical Director board certified in Gastroenterology, but that the previous coverage decision still could not be changed. The letter states in relevant part as follows:

> We cannot approve this request for Botox (also called botulinum toxin) on appeal review. Your doctor requested Botox for treatment of your gastroparesis (injection into the pylorus). Per Medical Policy DRUG. 00006, Botox is considered investigational FOR THIS DIAGNOSIS. It is not of proven benefit for uses in cases of poor stomach muscles squeezing. Appeal is denied. This decision was based on health plan Medical Policy Botulinum Toxin (DRUG .00006).

(Defs.' 56.1 Statement ¶37, AR 0481-84 (emphasis in original).)

C. The Third Appeal

On or about January 6, 2016, Plaintiff requested an independent external review of the claim for the Botox Injection administered on February 24, 2015. (Defs.' 56.1 Statement ¶38.)

She was advised that her request for external review had been submitted to AllMed and that she could submit any additional information that she wanted AllMed to consider. Plaintiff submitted a letter to AllMed dated January 21, 2016. In the letter she details her various ailments and how the Botox Injections, which are less invasive than her only alternative (viz. an electronic stimulator which requires major surgery), have greatly helped her in her day to day quality of life and have been therapeutic to her. (Defs.' 56.1 Statement ¶ 40; AR 676-78.)

By letter dated February 6, 2016, AllMed notified Plaintiff that it had upheld the denial of her appeal. The letter referenced the language in the Plan document regarding experimental/investigational treatments and stated that the principal reason for the decision was that "[p]er the plan language definition, the Botox injection on 2/24/15 is considered experimental/investigational as any treatment 'not proven in an objective manner to have benefits for the patient' and 'not recognized as acceptable medical practice in the United States' is considered experimental/investigational." Further, the letter stated:

> Currently, the use of Botox injections for gastroparesis is considered experimental/investigational and is not recommended by gastrointestinal practice guidelines. This treatment has been evaluated in multiple studies, and it is strongly suggested that Botox does not provided therapeutic benefits; future studies are unlikely to change this recommendation. Although the patient reported clinical benefit, treatment with Botox injections for gastroparesis is considered experimental/investigational and is not recommended as standard of care.

The letter cited three items in support of the decision: the Plan document, the article in the January 2013 American Journal of Gastroenterology that Plaintiff submitted to EHA and a 2010 article in a publication entitled Digestion.

(Defs.' 56.1 Statement ¶¶ 41-43; AR 772-75.)

V. The Instant Lawsuit

Plaintiff filed this action on July 6, 2016 asserting claims for breach of contract and violation of ERISA asserting that defendants wrongfully denied her benefits under the Plan. At the initial conference before the magistrate judge assigned to this matter, the parties agreed that no discovery was required and the matter could be determined on the record of the administrative proceedings. (DE 21.)[5]

---

[5] Despite that agreement, in support of her motion Plaintiff submitted a letter, dated February 24, 2017, from Larry Miller M.D., Chief of Gastroenterology, Northwell Health System. The letter states in full:

> The purpose of this correspondence is to provide explanation as to why endoscopy with botulinum toxin therapy is medically necessary and to share evidence from the patient's medical records and pertinent medical history that supports its clinical use. Attached, you will also find peer-reviewed literature on the treatment of gastroparesis with botulinum toxin therapy.
>
> Mary Ellen Walsh is a patient well known to me for the past year, she is a 46 year-old female with Refractive Diabetic Gastroparesis.
>
> Symptoms of gastroparesis began in 8/2013 when she started having vomiting. She was diagnosed with gastroparesis in 2014 and was treated with Botox. She responded to the Botox and was getting injections every 3 months until insurance would not pay for the Botox. This period of time for which the patient was unable to receive treatment of about 15 months, patient had developed extensive erosive gastritis.
>
> Her symptoms prior to the Botox included retching and vomiting 8 to 10 times a day and dehydration. She also complained of stomach spasm. After the Botox she would have retching and vomiting only 1 to 2 times per week and the abdominal spasm resolved. Her last three endoscopies with pylorus botox injection were in 4/29/2016, 9/19/2016 and 1/23/2017 and were successful in alleviating her symptoms. Without the botox therapy, patient would be incapacitated and her gastroparesis would interfere with daily functioning, as well as diminish her quality of life.
>
> It is respectfully requested that this service be deemed as a medical necessity, as it is clinically reasonable, necessary, and supported by clinical studies .

(DE 26-4.) It should be noted that the "peer reviewed literature" referenced by Dr. Miller was not filed with the Court.

Plaintiff's papers do not acknowledge that Dr. Miller's letter is not part of the administrative record and thus may not be considered absent good cause. *See, e.g., Krauss v. Oxford Health Plans, Inc.,* 517 F.3d 614, 631 (2d Cir. 2008) ("We have repeatedly said that a district court's decision to admit evidence outside the administrative record is discretionary, but which discretion ought not to be exercised in the absence of good cause.") (internal quotation marks omitted); *accord DeFelice v. Amer. Int'l Life Ins. Co. of N.Y.*, 112 F.3d 61, 66-67 (2d Cir. 1997). As she has provided the Court with no legal argument as to why good cause exists, it is not appropriate for this Court to consider it. *See Ramsteck v. Aetna Life Ins. Co.*, 2009 WL 1796999, *8 (E.D.N.Y. June 24, 2009). Even assuming that there is good cause to consider the letter, it would not change this Court's determination given the absence of the literature supporting his opinion and given that his letter addresses the medical necessity of the treatment as opposed to whether it is investigational.

DISCUSSION

I. Summary Judgment Standard

Summary judgment, pursuant to Rule 56, is appropriate only where admissible evidence in the form of affidavits, deposition transcripts, or other documentation demonstrates the absence of a genuine issue of material fact, and one party's entitlement to judgment as a matter of law. *See Viola v. Philips Med. Sys. of N. Am.,* 42 F.3d 712, 716 (2d Cir. 1994). The relevant governing law in each case determines which facts are material; "[o]nly disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment." *Anderson v. Liberty Lobby, Inc*., 477 U.S. 242, 248 (1986). No genuinely triable factual issue exists when the moving party demonstrates, on the basis of the pleadings and submitted evidence, and after drawing all inferences and resolving all ambiguities in favor of the non-movant, that no rational jury could find in the non-movant's favor. *Chertkova v. Conn. Gen'l Life Ins. Co.*, 92 F.3d 81, 86 (2d Cir. 1996).

To defeat a summary judgment motion properly supported by affidavits, depositions, or other documentation, the non-movant must offer similar materials setting forth specific facts that show that there is a genuine issue of material fact to be tried. *Rule v. Brine, Inc*., 85 F.3d 1002, 1011 (2d Cir. 1996). The non-movant must present more than a "scintilla of evidence," *Del. & Hudson Ry. Co. v. Consol. Rail Corp.*, 902 F.2d 174, 178 (2d Cir. 1990) (quoting *Anderson*, 477 U.S. at 252) (internal quotation marks omitted), or "some metaphysical doubt as to the material facts," *Aslanidis v. U.S. Lines, Inc.,* 7 F.3d 1067, 1072 (2d Cir. 1993) (quoting *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586-87 (1986)) (internal quotation marks omitted), and cannot rely on the allegations in his or her pleadings, conclusory statements, or on

"mere assertions that affidavits supporting the motion are not credible." *Gottlieb v. Cnty. of Orange*, 84 F.3d 511, 518 (2d Cir. 1996) (internal citations omitted).

The district court considering a summary judgment motion must also be "mindful . . . of the underlying standards and burdens of proof," *Pickett v. RTS Helicopter*, 128 F.3d 925, 928 (5th Cir. 1997) (citing *Anderson*, 477 U.S. at 252), because the "evidentiary burdens that the respective parties will bear at trial guide district courts in their determination[s] of summary judgment motions." *Brady v. Town of Colchester*, 863 F.2d 205, 211 (2d Cir. 1988). "[W]here the nonmovant will bear the ultimate burden of proof at trial on an issue, the moving party's burden under Rule 56 will be satisfied if he can point to an absence of evidence to support an essential element of the nonmoving party's claim." *Id*. at 210-11. Where a movant without the underlying burden of proof offers evidence that the non-movant has failed to establish her claim, the burden shifts to the non-movant to offer "persuasive evidence that his claim is not 'implausible.' " *Id*. at 211 (citing *Matsushita*, 475 U.S. at 587).

II. Standard of Review

As a threshold matter, the Court must determine the appropriate standard of review to apply to the denial of plaintiff's claim for benefits. The Supreme Court has made clear that "a denial of benefits challenged under § 1132(a)(1)(B) is to be reviewed under a *de novo* standard unless the benefit plan gives the administrator or fiduciary discretionary authority to determine eligibility for benefits or to construe the terms of the plan." *Firestone Tire & Rubber Co. v. Bruch*, 489 U.S. 101, 115 (1989); *see Muller v. First Unum Life Ins. Co.*, 341 F.3d 119, 123-24 (2d Cir. 2003) If such discretion is given, a district court must review the administrator's denial of benefits deferentially, and may reverse only if the administrator's decision was arbitrary and

capricious. *See Kinstler*, 181 F.3d at 249. Here, no discretionary authority was given to EHA and therefore the *de novo* standard applies.

"When applying the de novo standard of review, the Court reviews 'all aspects of the denial of an ERISA claim.' " *McDonnell v. First Unum Life Ins. Co.*, 2013 WL 3975941, at *11, (S.D.N.Y. Aug. 5, 2013) (quoting *Kinstler v. First Reliance Std. Life Ins. Co.*, 181 F.3d 243, 245 (2d Cir. 1999)). The Court gives no deference to the administrative interpretation of the plan documents or its conclusion regarding the merits of the claim, but rather "reaches its own conclusion about whether the plaintiff has shown, by a preponderance of the evidence, . . . entitle[ment] to benefits under the plan." *McDonnell*, 2013 WL 3975941, at *12.

III. Summary of Arguments

Plaintiff's argument centers on her claim that the treatment was medically necessary and that defendants wrongfully denied her treatment "in spite of objective evidence . . . that the treatment had therapeutic benefit dependent on dosage, in spite of reports by plaintiff that the medication relieved her symptoms . . . and despite that the treatment had been covered in the past. She also asserts that defendants "committed procedural error in failing to instruct plaintiff on how to perfect her claim . . . ." (Pl.'s Mem. (DE 26-3) at 3-5.)

Defendants maintains that the only claim ripe for review is the adjudication of the provider's claim regarding the fifth Botox Injection and that she lacks standing to challenge it because it affected only the provider, i.e. she incurred no cost as a result. Moreover, the plan does not cover Botox Injections because it is investigational for the treatment of gastroparesis. Finally, EHA complied with the regulations governing claims adjudication and the other defendants are not proper parties. (Defs.' Mem. (DE 27-3) at 10-13.)

IV. Summary Judge is Granted in Favor of Defendant EHS[6]

A. The Plan Does Not Cover Botox Injections for Gastroparesis

Analysis of this case begins with the terms of the Plan. It specifically provides that that it "does not pay benefits unless the charge is for services or supplies covered by the Plan" and that "the Plan does not pay for . . . Treatment that is experimental, investigational or part of a research program." (AR 130 & 132.) As noted earlier, the Plan defines "experimental or investigational" to include, among other things, "any treatment not proven in an objective manner to have benefits for the patient" "and/or" "any treatment, drug or supply which is not recognized as acceptable medical practice in the United States."

Rather than address the issue of whether the use of Botox Injections for the treatment of gastroparesis is investigational or experimental, Plaintiff asserts that the injections were medically necessary. That, however, is not the issue.[7] Coverage for services is governed by the terms of the Plan. Plaintiff, who bears the burden of proof in this matter, has failed to submit evidence demonstrating that Botox Injections for the treatment of gastroparesis were accepted as effective in peer-reviewed literature and therefore not investigational or experimental. Indeed, the journal articles contained in the administrative record at best point to the need for controlled trials to determine their efficacy in the treatment of gastroparesis. In other words, the literature supports the conclusion that such treatment is, or at least was at the relevant point in time,

---

[6] The claims against HMO and BC/BS are dismissed. The evidence demonstrates that HMO has no relationship to Plaintiff or with the Welfare Fund and that BC/BS is not a legal entity but rather a name under which EHA and HMO conduct business. (Langhorne Aff. (DE 27-4) ¶¶ 4, 5.) Plaintiff's unsupported assertions otherwise do not create an issue of fact.

[7] Even if the exclusion for investigational and experimental treatment could be overridden by medical necessity, there has been no showing of medical necessity as defined by the Plan. Among other things, the Plan includes in the criteria for determining medically necessary that "treatment is consistent with the symptoms and diagnosis of the patient's condition" and "is in accordance with standards of good medical practice." The use of an experimental treatment outside the confines of a controlled trial or research project would not necessarily be in accordance with standard good medical practice.

investigational or experimental. For example, the January 2013 article in the American Journal of Gastroenterology concludes that the "[i]ntrapyloric injection of [Botox] is not recommended for patients with gastroparesis based on randomized controlled trials. (Strong recommendation, high level of evidence)." (AR 455.) Similarly, an October 2004 article in Diabetes Care, submitted by Plaintiff in support of her appeal, recommends a blinded, placebo controlled trial to confirm the efficacy of Botox Injections for the treatment of gastroparesis. (AR 348.) While the record contains a 2004 interview of a Dr. Freidenberg recommending Botox for certain patients who have gastroparesis, that recommendation is based on a very limited study at Temple University and absent from the interview is any detailed analysis of the study or its findings. Thus, it is insufficient to sustain Plaintiff's burden. Indeed, her own doctor's notes, dated October 22, 2015, state "I am aware of a small double blind study which didn't show advantage to the treatment over placebo. In my opinion the study is too small to make a definite conclusion. There are reports of its beneficial effects. A study from the University of Michigan suggested that some people may need higher doses to respond." (AR 296-97.)

That the first four Botox Injections were covered does not change the Court's conclusion. The claims submitted by the provider for the first four injections sought reimbursement of "Surgery-Pharynx/Esph," and certain ancillary charges, but did not seek reimbursement for the botulinum toxin (the "Botox") that was injected into Plaintiff. Thus, Defendant cannot be estopped from asserting that Botox Injections for the treatment of gastroparesis is experimental/investigational.

In sum, Plaintiff has failed to submit sufficient evidence to sustain her burden of demonstrating that the subject treatment is covered under the terms of the Plan.

B. The Claim that Defendant Violated Applicable Regulations is Without Merit

Plaintiff's asserts that EHS violated "29 U.S.C. § 1132(a)(3) by failing to provide the 'specific reason or reasons for the adverse determination' and failing to give a 'description of any additional material or information necessary for the claimant to perfect the claim and an explanation of why such material or information is necessary' as required by statute." Pl.'s Mem. at 3-4.

29 C.F.R. § 2560.503-1(g) sets forth the requirements for benefit notifications. It requires, in pertinent part:

> The notification shall set forth, in a manner calculated to be understood by the claimant—
> (i) The specific reason or reasons for the adverse determination;
> (ii) Reference to the specific plan provisions on which the determination is based;
> (iii) A description of any additional material or information necessary for the claimant to perfect the claim and an explanation of why such material or information is necessary;
> (iv) A description of the plan's review procedures and the time limits applicable to such procedures, including a statement of the claimant's right to bring a civil action under section 502(a) of the Act following an adverse benefit determination on review;
> (v) In the case of an adverse benefit determination by a group health plan—
> > (A) If an internal rule, guideline, protocol, or other similar criterion was relied upon in making the adverse determination, either the specific rule, guideline, protocol, or other similar criterion; or a statement that such a rule, guideline, protocol, or other similar criterion was relied upon in making the adverse determination and that a copy of such rule, guideline, protocol, or other criterion will be provided free of charge to the claimant upon request; or
> > (B) If the adverse benefit determination is based on a medical necessity or experimental treatment or similar exclusion or limit, either an explanation of the scientific or clinical judgment for the determination, applying the terms of the plan to the claimant's medical circumstances, or a statement that such explanation will be provided free of charge upon request.

29 C.F.R. § 2560.503-1 (g).

Addressing first the argument that EHS failed to "give a 'description of any additional material or information necessary for the claimant to perfect the claim and an

explanation of why such material or information is necessary," it is rejected. Given the nature of the denial, there was no further information that was *needed* from Plaintiff. Indeed, while Plaintiff was free to conduct research into the use of Botox Injections for the treatment of gastroparesis, it would have been unrealistic for EHS to require her to do so.

The Court now turns to whether "[c]orrespondence from defendant to plaintiff regarding coverage decisions fails to provide any specific rationale for denial other than claiming that the treatment was not medically necessary and not proven effective." Plaintiff baldly makes this assertion without directing the Court's attention to where in the 776 page administrative record the referenced correspondence is found. (Pl.'s Mem. at 4.) Having independently searched the record for this correspondence, the Court's review thereof fails to yield any deficiencies.

The explanation of benefits sent to Plaintiff after the retrospective review advised her that the claim was 'determined to be investigational and/or not medically necessary," sets forth detailed information regarding the appeal procedure and notes that a "separate letter containing the details of the determination has been sent to [Plaintiff]." (AR 611-12.) That letter, dated April 7, 2015, states "*We cannot approve coverage for the use of Botulinum toxin. You have a condition called gastroparesis. . . . Your doctor used Botox to treat this problem. Medical studies have not shown that Botox is as good or better than other treatments for this condition. This drug is considered to be investigational for this use. Reference: medical policy DRUG.0006 Botulinum Toxin.*" The letter enclosed an explanation of the right to appeal and detailed instructions on appealing. (AR 645-652.)

The first level appeal decision denied the appeal and declined to change the previous coverage decision, stating,

> [T]he services are considered investigational as defined in the Details and Definitions section of your POS benefits booklet.
> *We cannot approve coverage for the use of Botulinum toxin. You have a condition called gastroparesis. . . . Medical studies have not shown that Botox is as good or better than other treatments for this condition. This drug is considered to be investigational for this use. We based this decision on your health plan's medical policy DRUG.0006 Botulinum Toxin. . . .*
> You can find our medical policies and clinical guidelines online:
> - Visit our website www. Empireblue.come/home providers.html; and
> - Click Learn More under Medical Policies (upper right hand side of the web page).
> -

(AR 626 (emphasis in original.) The decision also advised Plaintiff of her right to a second level appeal and an independent external review and sets forth the procedure for proceeding under either option. (AR 628.)

The decision at the second level of appeal advised Plaintiff that, after review by a Medical Director board certified in Gastroenterology, the previous coverage decision would not be changed as "[t]he services are considered investigational as defined in the Exclusions and Limitations section of you Empire POS Benefit Booklet." The letter goes on to advise Plaintiff where the medical policies and guidelines can be found and advised her of her right to bring a civil action under ERISA. (AR 482-83.)

Finally, the letter from AllMed, which conducted the independent external review by a physician board certified in Gastroenterology and Internal medicine, similarly advised Plaintiff that the subject Botox Injections were experimental/investigational, lists all the documents considered, provides the rationale for the decision, and lists all the evidence-based standards and coverage provisions that were relied upon in making the decision. It also advised Plaintiff of her right to file a lawsuit. (AR 773-776.)

Having reviewed each level of determination, there is no basis to conclude that EHS did not comply with the referenced regulation.

CONCLUSION

For the reasons set forth above, Plaintiff's motion for summary judgment is denied and Defendants' motion for summary judgment is granted. The Clerk of Court is directed to enter judgment accordingly and to close this case.

SO ORDERED.

Dated: Central Islip, New York
May 22, 2018

s/ Denis R. Hurley
Denis R. Hurley
United States District Judge